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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,956	04/12/2002	Mark Sanders	301.1003	3247

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,956	SANDERS, MARK	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Preliminary Amendment received on April 12, 2002 is acknowledged. Claims **1-29 and 34** are pending in this application. Claims 30-33 and 35 stand cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites, "the respiratory disorder is COPD" which is vague and indefinite.

Claims 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

The examiner suggests specifying the components in the formulation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17-18 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Britto (6,253,762) optionally in view of in view of Carling et al (5,674,860).

Britto teaches a metered does inhaler for fluticasone propionate. The drug formulation is made into a fine powder and suspended in a propellant. See column 1, lines 20-25. Fluticasone is optionally combined with one or more pharmacologically active ingredients such as anti-inflammatory agents, analgesic agents, or other respiratory agents. A particularly preferred drug formulation is fluticasone in combination with a bronchodilator. Bronchodilators taught are salbutamol, salmeterol, ephedrine, adrenaline, fenoterol, formoterol, etc. See column 3, lines 20-57. The examples disclose fluticasone and bronchodilator (salmeterol) combination. The formulation contains excipients such as surfactants, co-solvents, and propellants. See column 3.

Britto does not exemplify the instant bronchodilator in combination with fluticasone.

Carling et al teach a combination of a bronchodilator and a steroidal anti-inflammatory for the treatment of respirators diseases such as asthma. See abstract.

Carling teaches a combination of formoterol and budesonide. Formoterol is taught as the bronchodilator which acts rapidly to provide immediate relief for the patient. Instant formoterol salts are taught on column 3, lines 30-38. Furthermore, Carling states that the prior art bronchodilators are that they have a short duration of action whereas formoterol has a longer duration and it is possible to avoid nocturnal asthma. Formoterol provides less nocturnal waking than the common bronchodilators such as salbutamol, terbutaline, and the like. See column 2, lines 4-20. The two actives may be administered simultaneously, sequentially, or separately. See column 2, lines 29-35. The suitable dose of formoterol is 6-100 micrograms twice a day. However, the particular dose depends on the patient and severity of the disease. See column 3, lines 43-50.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look at the guidance provided by Britto and utilize a composition containing fluticasone and formoterol. One would be motivated to do so since Britto teaches a preferred combination of actives is fluticasone and bronchodilators. Although, Britto does not exemplify formoterol, Britto states that formoterol is a bronchodilator and may be combined with fluticasone. Therefore, one would be motivated to use the instant bronchodilator with similar results. Furthermore, one could reasonably expect success since the art teaches the functional equivalency of the instant bronchodilator and Britto's exemplified bronchodilator (salmeterol) and it is obvious to substitute one functionally equivalent compound with another functionally equivalent.

Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Britto and Carling et al and utilize fluticasone and instant bronchodilator. One would be motivated to do so since Carling et al teach the instant bronchodilator has a longer duration of action to provide less nocturnal waking than conventional bronchodilators. Further, Carling states that the instant bronchodilator acts rapidly to provide immediate relief. Therefore, one would be motivated to use formoterol due to the advantages taught by Carling.

*Note that the step of administering the composition does not have patentable weight in a product claim.

Claims 1-10, 16-29, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer (5,270,305) in view of Carling et al (5,674,860).

Palmer teaches a composition containing salmeterol and fluticasone to treat asthma and other respiratory disorders. See column 1, lines 5-6. Asthma is treated using a bronchodilator for immediate relief and a prophylactic anti-inflammatory corticosteroid to treat underlying inflammation. Salmeterol is taught as a bronchodilator and fluticasone is taught as an anti-inflammatory corticosteroid. See column 1, lines 65-68. The active compositions are combined for simultaneous, sequential, or separate administration. See column 2, lines 35-38. Suspensions of aqueous solutions are administered via a nebulizer. An aerosol is prepared with a propellant and stabilizers. Further, the dry powder composition may contain a suitable carrier such as lactose and administered via an inhaler. See column 3, lines 9-20.The suitable does of fluticasone for inhalation is 50 to 200 micrograms and 25 to 100 salmeterol. The dosage depends

on the severity of the disease and conditions of the patient such as age, weight, etc. see column 3, lines 20-38.

Palmer does not teach the instant bronchodilator, formoterol.

Carling et al teach a combination of a bronchodilator and a steroidal anti-inflammatory for the treatment of respirators diseases such as asthma. See abstract. Carling teaches a combination of formoterol and budesonide. Formoterol is taught as the bronchodilator which acts rapidly to provide immediate relief for the patient. Instant formoterol salts are taught on column 3, lines 30-38. Furthermore, Carling states that the prior art bronchodilators are that they have a short duration of action whereas formoterol has a longer duration and it is possible to avoid nocturnal asthma. Formoterol provides less nocturnal waking than the common bronchodilators such as salbutamol, terbutaline, and the like. See column 2, lines 4-20. The two actives may be administered simultaneously, sequentially, or separately. See column 2, lines 29-35. The suitable dose of formoterol is 6-100 micrograms twice a day. However, the particular dose depends on the patient and severity of the disease. See column 3, lines 43-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Palmer and Carling et al and utilize fluticasone and instant bronchodilator. One would be motivated to do so since Carling et al teach the instant bronchodilator has a longer duration of action to provide less nocturnal waking than conventional bronchodilators. Further, Carling states that the instant bronchodilator acts rapidly to provide immediate relief. Therefore, one would be

motivated to look to Carling et al and substitute Palmer's bronchodilator with formoterol due to the advantages taught by Carling. One would expect similar results since both references teach a steroid anti-inflammatory and a bronchodilator for respiratory disorders such as asthma.

Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer (5,270,305) in view of Carling et al (5,674,860) in further in view of WO 97/47286.

As set forth above, Palmer teaches a composition containing salmeterol and fluticasone to treat asthma and other respiratory disorders. Carling et al teach a combination of an instant bronchodilator and a steroidal anti-inflammatory for the treatment of respirators diseases such as asthma.

The references do not teach the instant propellant.

WO teaches a medicinal aerosol formulation of formoterol. The reference teaches the undesirability CFCs the environment and HFAs are viewed as more ozone friendly. Further, HFAs have low toxicity and vapor pressures suitable for use in aerosols. See page1, lines 13-18. Furthermore, the instant HFA 227 and HFA 134 provide a stable propellant system and HFA 227 is beneficial to producing homogenous suspensions. See page 3 and 5.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Palmer, Carling et al, and WO and utilize the instant propellant. One would be motivated to do so since WO teaches the advantages that the instant propellant system provides. Therefore, one would be motivated to use HFA to

provide a stable propellant system and a homogenous suspension of the drug and propellant. One would expect similar results since Palmer also teaches the use of propellants when administering the composition via an aerosol system.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

January 20, 2004

MICHAEL G. HARTLEY
PRIMARY EXAMINER